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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LAYNO, CARL HERNANDZ	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/804,471	HAEFNER, PAUL	
	Examiner	Art Unit	
	Carl H. Layno	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,24,29-37 and 43-45* is/are rejected.

7)☒ Claim(s) *18-23,25-28 and 38-42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/26/04,2/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. Acknowledgment is made of applicant's Information Disclosure Statements (PTO-1449s), which were received by the Office on July 26, 2004 and February 14, 2005.

Drawings

2. Applicant's formal drawings were received by the Office on March 19, 2004 and have been approved of by the Examiner.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-16, 29, 30, and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claim 1 is indefinite in that the statement "the sensed signal" (line 10) is ambiguous. The Examiner does not know if this refers to a sensed "electrocardiogram signal" detected at the subcutaneous non-intrathoracic location or the "received signal" associated with the non-electrophysiological cardiac source. Claims 2-16 are also rejected since they depend from rejected base claim 1.

In regard to claims 29 and 30, the statement "detecting presence or non-presence of the cardiac arrhythmia " (lines 1-2), has no antecedent basis. Base claim 17 recites the step of "detecting a cardiac arrhythmia", not separately sensing for its "non-presence" (i.e. absence, presence of normal sinus rhythm, etc.). The presumption of claim 17 is that a cardiac arrhythmia has already been detected using the sensed ECG signal.

In regard to claim 44, line 1, there is no antecedent basis for the term "the discriminating means". To overcome this rejection, the Examiner recommends replacing this with the term "means for detecting".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 16, 17, 30-35, 43, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Hauser et al (US 6,280,462) (Applicant's prior art).

In regard to claims 1, 17, 35, and 43, the Hauser et al (US 6,280,462) patent, cited by the applicant as prior art, describes an implantable heart treatment and monitoring device (Fig.6) having embodiments whose methods of operation read upon applicant's claimed method steps.

Specifically, the device of Hauser et al includes a surface electrode **14**, mounted on the outer surface of the device's housing **10** (Figs.1, 3, 4, and 17). The device may be located subcutaneously in a patient's pectoral or abdominal regions rather than near a patient's heart (col.5, lines 49-52); consequently, the Examiner considers its location to be non-intrathoracic. Although intracardiac electrodes **28** and **29** (Fig.6 -- col.5, lines 42-43) normally sense the patient's cardiac signals (i.e. ECG), the surface electrode **14** on the device housing also may be used for sensing (Abstract, lines 8-10), or may be used as a replacement for "one of [these] intravascular catheter electrodes" (col.5, lines 55-58). In addition to this sensor, the device of Hauser et al includes a temperature sensor **19** for sensing the temperature inside the body/heart, which performs the function of applicant's "non-electrophysiologic" signal. The temperature sensor validates the presence of a true cardiac signal versus noise on the sensors inputs since it alerts the device when the device is actually implanted within the body (col.5, lines 5-17) and withholds the delivery of stimulation therapy (i.e. defibrillation shock) if the device is located outside the body (i.e. falsely responding to sensed ambient noise). Surface electrode **14** may selectively be picked by switch **14** to act as a defibrillation electrode in the event that a shock is to be delivered to the patient (col.6, lines 18-20). The device of Hauser et al includes a cardiac detection circuit **84** (Fig.16) for distinguishing normal sinus rhythm from other abnormal sensed cardiac signals (e.g. cardiac arrhythmias) (col.7, lines 18-20).

In regard to claims 16, 30, 31, 33, 34, and 45, the Hauser et al device generates pacing, cardioversion, or defibrillation therapy in response to detected heart signals (e.g. bradycardia, tachycardia, etc. – col.7, lines 14-15) other than normal sinus rhythm. Applicant's attention is also directed to col.7, lines 18-23.

In regard to claim 32, the pulse generator **18** of Hauser et al inherently performs the function of applicant's "processor" since it is has the "full-function pacing capabilities" of a pacer (col.7, lines 13-14).

In regard to claim 35, temperature sensor **19** is located within the device housing **10** (Fig.2).

In regard to claim 45, all electrical therapy treatments delivered by the Hauser et al device are done so subcutaneously since it is an implantable device.

7. Claims 1, 2, 8, 10, 11, 14, 15, 17, 24, 31, 32, 33, 36, 37, and 43-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Nelson et al (WO 03/020367 A1) (Applicant's Prior Art).

In regard to claims 1, 2, 8, 17, 24, 36, 37, 43, and 44, the Nelson et al WIPO patent WO 03/020367 A1, cited by the applicant as prior art, describes an implantable therapy device **10** (Fig.1) for detecting and treating myocardial ischemia, which appears to read upon applicant's method and apparatus claims. The Nelson et al device includes a plurality of ECG/EGM sensing electrodes (**16,18,20,22,24,26**) (Fig.1 – See Abstract) located on the outer housing of device **10** and a lead mounted accelerometer **108** (Fig.5) or pressure transducer (p.9, lines 21-22) for sensing heart activity. The device **10** is considered to be located in a non-intrathoracic area of the body since it can be implanted in the lower abdominal region (p.7, line 11). The applicant's attention is directed to the flow charts of Figs.9 and 10, which show signal discrimination between a normal signal (i.e. normal sinus rhythm) and an ischemic signal using ECG signals and those sensed by the accelerometer/pressure transducer. Note that therapy is withheld from

the patient (boxes **144** and **160**) unless the accelerometer criterion (boxes **140, 156**) are first satisfied (i.e. a proper cardiac ischemic signal).

In regard to claim 10, the Examiner considers the accelerometer sensed activity signals (**136,152**) (Figs.9 and 10) to be "subsonic".

In regard to claims 11 and 25, the accelerometer could be a pressure transducer (p.9, lines 21-22).

In regard to claims 15 and 33, the medical therapy device **10** may be a cardioverter or defibrillator (p.6, lines 27-28).

In regard to claim 31, cardiac therapy is delivered to treat the heart (boxes **144** and **160** of Figs.9 and 10).

In regard to claim 32, in addition to the structure mentioned *supra*, the therapy device includes a processor **110** (Fig.5) and an energy delivery circuit **114**.

In regard to claim 45, since the therapy device is implanted, all of its treatments are delivered "implantably".

Allowable Subject Matter

8. Claims 3-7, 9, 12, 13, and 29 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9. Claims 18-23, 25-28, and 38-42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Carl N. Layno

CARL LAYNO
PRIMARY EXAMINER

CHL
8/4/2006